

REMARKS

Claims 11 to 14 have been canceled and new claims 15 to 18 are being presented with this Amendment.

In order to avoid the objection to the omission of the article "A" in claim 11, new claim 15 begins with the article "A".

New claim 15 recites the expression: "and forming through the buccal cavity and on the user teeth an oil film resistant against water rinsings". These words do not add new matter since they have been used in the specification, for example on page 3, lines 3 to 9. Moreover, to form a water rinsing oil film through the buccal cavity and on the user's teeth, as disclosed in the introductory part of the specification, constitutes one of the main objects of Applicant's invention, which object has neither been taught nor suggested by any of the cited prior art. The prior art compositions cannot produce the effects of the claimed composition because they are very different from Applicant's mouthwash antibacteric composition as pointed out by new claims 15 to 18. The expression "adapted to form stable emulsions" has not been included in new claims 15-18.

Claim 11-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wright in view of Pianotti and Kunz et al. (Kunz).

Reconsideration is requested.

The Examiner applied Wright as teaching antibacterial oil-in-water emulsions (title). The emulsions are stable when heated or exposed to significant levels of acid and base (column 2, lines 56-57), encompassing instant claim 14. The emulsions

can be used in pharmaceutical preparations, made up of an antibacterial emulsion and a pharmaceutically acceptable carrier (column 2, lines 58-65). The Wright preparations were taught for application to oral surfaces, for example, as a mouthwash (column 3, lines 1-5). Oils useful in forming oily discontinuous phase of said emulsions include vegetable oils, such as soybean oil, canola oil, glycerol esters and mixtures thereof (column 2, lines 19-22). Said oily phase includes cetylpyridinium chloride (antiseptic substance) (column 2, lines 29-32). The amounts of oil phase to water phase range from 1:4 to 1:2 on a volume to volume basis (column 4, lines 35-38). The Eer concluded that the Wright compositions were encompassed by canceled claim 11.

Applicant does not agree with the Examiner's interpretation of Wright. In fact, Wright does not teach or suggest as a main element of its product the simultaneous presence of oil-phase antibacteric substances and water-phase antibacterial substances as pointed out in new claim 15.

In fact Wright teaches the use of a C12-C16 halogenated cationic compound which also has an antibacterial action, as an emulsifying substance. An example of such an antibacterial substance is cetylpyridinium chloride. This compound is a water soluble compound which is actually freely soluble in water.

Accordingly, Wright does not teach or address, in all its examples an oil-soluble antibacterial substance. Wright only discloses antibacterial emulsions, without disclosing or mentioning the reasons thereby these antibacterial emulsions actually have such an activity, which from the

examples of this patent, seems to be exclusively due to the halogenated cationic compounds.

With respect to the oil/water ratio, it is acknowledged that between Applicant's invention and Wright, there is a partial overlapping, due to the applicant's ratio being 1:20 to 1:1.5 and Wright's ratio being from 1:4 to 1:2 (column 4, lines 36-38 of Wright).

On the other hand, a main feature of Applicant's mouthwash composition, is that Applicant's emulsion provides an improved binding of the product to the buccal mucosa, while providing a protective film which is only slightly removed by water rinsings or by the user's saliva. This provides the claimed compositions with a prolonged duration of activity.

The prolonged activity feature of the claimed compositions is neither disclosed nor suggested as a main feature by the compositions of the Wright patent.

With respect to the Pianotti patent, the Applicant wishes to point out that Pianotti discloses an antimicrobial composition in the form of a mouthwash comprising a water-alcohol phase in which essential oils are dissolved, these essential oils comprising thymol, eucalyptol, methylsalicylate, mentol.

The claimed mouthwash composition, as disclosed in new claims, does not comprise essential oils but vegetable oils, mineral oils, aromatic oils and aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons.

The oils use in the claimed compositions, which constitute the base of the claimed

antibacterial mouthwash compositions, are not essential oils and are contained in a comparatively high amount as from 5 to 40% of the oils are present in a stable emulsion as an oil-in-water (O/W) emulsifying system. The oils used by Pianotti are essential oils that are used in a very small amounts, i.e. 0.05%-10%, as active antibacterial principles that are dissolved in a high water-alcohol phase.

Pianotti's mouthwash composition and that of the presently claimed mouthwash composition, operate in a very different manner: in fact, the claimed composition provides an oil film that adheres to the surface of the mouth cavity whereas the Pianotti mouthwash is not designed or adapted to provide this strong adhesion property, since it is a traditional mouthwash composition which is easily removed when the inner mouth cavity is rinsed.

With respect to Kunz, this patent discloses and claims compositions for continuously transporting a bioactive agent through a biologic membrane. On the contrary, Applicant's mouthwash composition of new claims, is an emulsion which must adhere to the oral mucosa (and is not transported therethrough) for a long time to continuously provide an antibacterial action.

Kunz does not teach or suggest the use of antibacterial or disinfecting agents and the like, as it is limited to the delivery bioactive agents or nucleic acids through a biologic membrane.

It is acknowledged that, as observed by the Examiner on then last six lines of page 5 of the Office Action, that the Kunz composition may be delivered orally. However, such an oral delivery actually involves swallowing and ingesting the Kunz

composition, whereas Applicant's mouthwash composition is used as a conventional mouthwash, that is only for rinsing the oral or buccal cavity and it is neither swallowed nor ingested.

With respect to the further observation of the Examiner that "Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used the mouthwash composition comprising a water-alcohol mixture, fluoride, saccharine and xylitol as the aqueous pharmaceutical carrier of Wright and oils such as mineral oils, aromatic oils, aliphatic hydrocarbons, triglycerides, hydrocarbons comprising esters and ethers in mixture in the oil phase in addition to those disclosed by Wright when formulating an oil-in-water mouthwash motivated by the desire to use a vehicle known in the art as suitable for mouthwashes, as disclosed by Pianotti, and oils suitable for use in the oil phase of oil-in-water emulsions as disclosed by Kunz at al. and supported by MPEP 2144.07". The Applicant respectfully submits that it would not have been obvious to combine the above mentioned patents to achieve Applicant's mouthwash compositions without the Applicant's disclosure. The Wright patent is concerned with an orally applied emulsion for treating a specific bacteria while Pianotti and Kunz are not concerned with emulsions or the organism that is disclosed in the Wright patent. In fact no such combined product is commercially available.

Accordingly, the Applicant wishes to stress that all of the new claims disclose a novel and

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unobvious antibacterial mouthwash composition.

In view of the foregoing discussion and the newly presented claims, allowance of the application is respectfully solicited.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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